UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/671,640
Applicant	:	GLENN, Bradley J.
Filed	:	09/26/2003
TC/A.U.	:	3733
Examiner	:	PHILOGENE, Pedro
Docket No.	:	3121.001

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.131

I, Bradley J. Glenn, declare as follows:

1. I am one of the co-inventors of the above-identified patent application.

2. I am a medical doctor, board certified as a physician in radiology, interventional radiology and neuro radiology. As such I have experience in the implementation of medical devices into the human body.

3. In January 2000 I conceived of a basic idea for stabilizing adjacent vertebrae of the spine through implantation of a stabilization device in a minimally invasive surgical procedure. The original conception generally involved the idea of providing two elongate elements such as dowels and implanting them through two posterior lateral incisions on either side of the spine. The two dowel-like elements would pass into the intervertebral space and would cross each other within this intervertebral space to distract the two adjacent vertebrae away from each other and stabilize the two adjacent vertebrae while bone and growth media solidifies to fuse the adjacent vertebrae

together. One reason for my interest in this invention at this time was that I was considering undergoing a spinal surgery procedure myself.

4. In March and April 2000 I had meetings with co-inventor Gary Schneiderman as he was preparing to perform a spinal surgery procedure on my spine. The lumbar surgery procedure occurred on April 24, 2008.

5. On May 18, 2000 I met with Dr. Schneiderman at Paragary's restaurant in Sacramento, California. We discussed my conceived invention and we discussed refinements to the invention. We decided to partner together to develop and license the invention.

6. Attached as Exhibit A is a copy of a credit card statement for my First USA credit card showing a purchase at Paragary's restaurant on May 18, 2000 in an amount typical for a two person lunch. Confidential credit card information has been redacted.

7. On July 14, 2000, the conceived design had crystallized sufficiently that I determined to purchase materials for construction of a prototype. On July 14, 2000 I went to the Michael's store in Vacaville, California. Michael's is a miscellaneous craft supply store. I purchased styrofoam and balsa wood for construction of such a prototype device. Attached as exhibit B is a page of my MBNA (Maryland Bank National Association) credit card records dated July 2000 and illustrating purchase of goods from Michael's on July 14, 2000. Confidential credit card information has been redacted.

8. The same evening (July 14, 2000) that the materials were purchased, I shaped the materials into prototypes of the invention at my home in California. At the end of this day an oversized prototype formed of styrofoam was completed. The timing of the styrofoam prototype creation is clear to me because I recall well my wife's surprise that I immediately went to work on the prototype after obtaining the materials.

9. I tested the prototype as soon as it was completed. Such testing included orienting the two elements of the prototype along intersecting paths, and passing the secondary element through the primary element and rotating the secondary element to verify clearance, interlocking strength and stability of the prototype.

10. The only differences between this styrofoam prototype and an actual basic implant that could perform according to the method of this invention was that the prototype needed to be sized to fit the patient's anatomy and formed of a biocompatible material. Such sizing and material substitution steps are merely steps in perfecting the invention. Thus, the invention was completed by reduction to practice in the United States on July 14, 2000.

11. Two or three days later, I showed this first styrofoam prototype to the co-inventor, Gary Schneiderman. He was also able to handle and manipulate this styrofoam prototype in the same general fashion that it would be manipulated during surgery and according to the method of this invention. Dr. Schneiderman considered this styrofoam prototype to show that the invention that we previously jointly conceived had the capacity to perform in the manner intended.

12. Dr. Schneiderman was concerned that the styrofoam prototype was perhaps too crude to convince investors as to the sophistication of our partnership and that a smaller size closer to that to be used for a commercial implant would enhance our marketing efforts.

13. For such a smaller prototype, balsa wood was considered to be the material of choice. I formed the second prototype of balsa wood having approximately accurate dimensions for utilization to stabilize adjacent vertebrae of the human spine. Otherwise, the proportions of the styrofoam prototype and the balsa prototype were similar. Photographs of this prototype are attached as Exhibits C, D and E.

14. The smaller balsa prototype took me two weeks to create. The smaller size and frequent breakage contributed to this difficulty.

15. The balsa prototype was more effective to market the invention and so the styrofoam prototype was not kept.

16. The testing performed upon completion of the styrofoam prototype and the completion of the smaller balsa prototype, convinced me as well as Dr. Schneiderman that the invention was ready for commercialization. Thereafter, and leading up to August 20, 2000, a Power Point presentation was prepared and meeting set up with the Sulzer-Spinetech medical device company of Winterthus, Switzerland. This meeting was originally scheduled for August 2000 but was later rescheduled for January 2001.

17. On October 12, 2000 an initial consultation was conducted with a registered patent attorney, Mr. Bradley P. Heisler, along with Dr. Schneiderman. The balsa prototype (Exhibits C, D and E) was given to Mr. Heisler. Thereafter, a patentability search was performed, and a patent application was prepared, reviewed and filed on March 27, 2001 that was the parent application for which this application was a continuation.

18. Mr. Heisler was able to draft the patent application based on physical examination of the balsa prototype. After filing the patent application, a second medical device company, DePuy Spine, Inc. of Raynham, Massachusetts did enter into a contract with Dr. Schneiderman and myself to commercialize this invention. DePuy Spine made this decision to enter into this commercialization agreement without requiring any further construction or testing of additional prototypes other than the second balsa prototype (Exhibits C, D and E) and drawings from the patent application and other drawings corresponding with the balsa prototype.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further

that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully Submitted:

Bradley J. Glenn, M.D.

12/16/08
Date